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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/379,308	08/23/99	DIAZ	P 016800-318

021839 HM12/0418
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EXAMINER	
LUKTON, D	
ART UNIT	**PAPER NUMBER**
1653	5

DATE MAILED: 04/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/379,308	Diaz
Examiner	**Group Art Unit**
David Lukton	1653

☒ Responsive to communication(s) filed on *Jan 20, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *28-30, 34-36, and 38-41* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *28-30, 34-36, and 38-41* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892 (attached)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Pursuant to the directeives of paper No. 4 (filed 1/20/00), claims 31-33 and 37 have been cancelled, and claims 38-41 added. Claims 28-30, 34-36, 38-41 are pending.

Applicants' arguments filed 1/20/00 have been considered and found persuasive in part. The previously imposed §112, second paragraph rejections are withdrawn. However, the §112, first paragraph rejection is maintained.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-30, 34-36, 38-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' representative has traversed this ground of rejection by arguing that the compounds underlying the method-of-use claims have the same biochemical properties as retinoids, and that therefor all of the method claims are enabled. However, applicants' representative has mischaracterized what is stated in the specification. The following is what is stated on page 17, lines 11+:

"The compounds... show activity in the test [described in *CANCER RESEARCH* **43**,

5268, 1983] **and/or** in the test of ornithine decarboxylase [inhibition as described in *CANCER RESEARCH* **38**, 793, 1978]"

Thus, there is no statement that the compounds exhibit activity in accordance with what is described in Strickland (*CANCER RESEARCH* **43**, 5268, 1983). The statement at issue could be interpreted to mean that the only experiments undertaken were those which demonstrated inhibition of ornithine decarboxylase. Applicants' representative has also made reference to a French patent application. First, this is (presumably) an application number, rather than a published document. Second, it is written in French, and third, no copy has been made of record. Thus, it is impossible for this examiner to determine what might be in that document. Accordingly, any arguments based on the contents of application 95/07302 will be set aside. At the present time, the assumption will be made that some of the compounds can inhibit ornithine decarboxylase; however, no assumptions will be made that the compounds are agonists of the retinoic acid receptor. It is suggested that applicants submit a declaration describing the assay which was conducted, accompanied by a statement that some of the compounds at issue were active in the assay. Applicants do not necessarily need to reveal which compounds were tested. At the present time, however, there is no affirmative, unequivocal statement by applicants that would lead one to believe that the compounds are indeed agonists of the retinoic acid receptor.

In addition, applicants should point to the specific documents which support the contention that compounds which inhibit ornithine decarboxylase or which are agonists of the retinoic

acid receptor can be used to treat arteriosclerosis, diabetes, hypertension, and all of the various known diseases of the eye (as in claim 41).

The rejection is maintained at the present time, but will be reconsidered after applicants have provided the information described above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800